endTB Clinical Trial
Pregnant Partner Consent Form

Version 3.3 Version Date: 14 February 2019

Subject Identification

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) - France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Partner Study Subject ID: _____

About this consent form

Please read this form, called pregnant partner consent form, carefully. It tells you important information about a research study. The purpose of this form is to request your consent to follow the progress of your pregnancy and the birth and health of your baby. A member of our research team will also talk to you about this research study.

If you have any questions about the research or about this form, please ask us. Signing this form is voluntary; it is up to you to decide whether to agree to the collection of this information or not. If you agree to the collection of this information, we will ask that you sign this form to confirm that you want to take part. We will give you a signed copy of this form to keep. You can decide not to share any information with this research study at any time if you do not want to, even after signing this form.

If you are not able to sign the consent form, but you would like to provide information, you can choose someone you know to sign for you and you can make a thumbprint to show that you understand the study and would like to take part.

Introduction

Your partner is or has been taking part in the research study called the endTB clinical trial. Some of the drugs that your partner is taking for this research may move into the semen. This is why when he started in the study, your partner was asked to use birth control while taking the study drugs. The effects of your partner's study medications on pregnancy and the developing fetus (baby still in the womb) are currently not known or not fully understood. For this reason, we would like to collect medical information about your pregnancy and the birth and health of your baby. We want to follow your pregnancy and try to find out if the study medications have any effect on your pregnancy and the health of your baby.

What will happen if I agree to provide information about my pregnancy?

If you agree to sign this consent form, we will review and collect medical information relating to your pregnancy, the delivery of your baby and the health of your baby at least at 6 and 12 months of age for any important medical issues.

Will anything bad happen to me?

Risks of Providing Information about Your Pregnancy:

We are careful to protect the identity of the people to the extent permitted by law. We also keep your and your baby's information secure and confidential. Electronic study information will be password-protected, and paper files will be stored in a locked office at [Research site]. Your and your baby's records will be kept at the clinic/hospital for XX years [*to be adapted locally*] following the completion of the study. If needed to monitor the trial quality, your and your baby's information and other information about you may be looked at by institutions responsible for quality and privacy such as the sponsor, Ethics Committee and Competent Authorities.

For the study, we will store some non-medical information about you and your baby, such as date of birth and city of residence. You can ask us to access, modify, complete, update, or delete this information. If you have any complaints about the protection of your data, you could contact your local/national Data Protection Authority [*Name and contact to be adapted locally*].

The information collected for this study will be used for the following purposes:

- For the purpose of this research. The sponsor, the study doctor, or other doctors involved in the study may publish reports or articles on the study or present the study findings to scientific groups. After the study is completed you may see your and your baby's records, and you may be told the results of the study.
- Secondary use for TB research; yours and your baby coded information may be used and shared with other institutions only for the purpose of further TB research during and after completion of the study and notably with the World Health Organization.

In all cases your identity will never be disclosed.

Your and your baby's coded information may be sent electronically to other researchers or institutions, If sent, it will be encrypted (scrambled so it cannot be read by people who should not see it).

We guarantee that, when we send your coded information, it will be protected according to European Economic Area standards.

What are the possible benefits?

There are no direct benefits to you or your baby for providing information relating to your pregnancy. However, we hope that the information we gather about your pregnancy will help future patients and their children by helping us understand the potential effects of the study medications on pregnancy women and developing babies.

What should I do if I want to stop providing information about my pregnancy?

If you decide you want to stop providing information to this study or if you change your mind later, you should tell us.

Information collected from you will be used to help answer study questions. When you leave, your information previously collected will still be used and stored for 20 years for the study and future TB research. However, if you prefer this information not to be used and destroyed, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will I be paid to provide information about my pregnancy?

This study will not cover any costs related to your pregnancy, delivery or care of your baby.

What will I have to pay for if I provide information about my pregnancy?

The sponsor will cover the costs of collecting your or your baby's medical information. There will be no cost or payment to you.

Who can I speak to if I have questions, concerns or complaints?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[PI Name and title] is the person in charge of this research study. You can call him/her at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions about this research study. If you have questions about the scheduling of appointments, call [Study Coordinator] at [SC number].

If you want to speak with someone not directly involved in this research study, please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

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Informed Consent and Authorization

Your signature on this document means the following:

I have read this consent form. I have had the reasons explained to me as to why data with regard to the pregnancy, the delivery and the health of the baby are required. I have had the opportunity to ask questions. I understand the information given to me. I will receive a complete, signed, dated copy of this informed consent form.

By signing below, I freely agree to allow the data concerning the pregnancy and the outcome of this pregnancy to be held on the Doctors Without Borders Drug Safety Database and being forwarded to regulatory agencies as necessary.

Signature of Pregnant Partner

_____ _____ _____

Signature or thumbprint of pregnant partner Date (DD/MMM/YYYY) Time

_____

Name of pregnant partner, printed in capital letters

Witness (if applicable):

_____ _____ _____

Signature of witness Date (DD/MMM/YYYY) Time

_____

Name of witness, printed in capital letters

Subject Identification

Study representative who obtained informed consent:

A verbal explanation of the research project, including drugs involved, risks and reasons why Doctors Without Borders is seeking data with regard to the outcome of the pregnancy, has been given to the person named above and I believe they understood that explanation. A copy of this signed and dated Pregnancy Data Release Form will be provided to the above named for their record.

_____ _____ _____

Signature of representative Date (DD/MMM/YYYY) Time

_____

Name of study representative, printed in capital letters